21st Century Cures Act: Interoperability, Information Blocking, and the ONC Health IT Certification Program Final Rule

Presented by

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The Office of the National Coordinator for
Health Information Technology

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Updates to the 2015 Edition Certification Criteria

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Time-Limited and Removed Criteria

- Drug formulary/Drug List Checks
- Patient-Specific Education
- Secure Messaging
- Problem List, Medication List, Med Allergy List
- Smoking Status

- Common Clinical Data Set summary record – create & receive criteria (replaced with USCDI)
- API (replaced with Standardized API criterion)
- Data Export (replaced with EHI export criterion)

Revised Criteria

- Interoperability criteria (C-CDA, VDT, etc.)
  - Updated with USCDI
  - Updated with C-CDA Companion Guide
- ASTM criteria

- Security tags send & receive criteria
- Electronic Prescribing (aligned with CMS)
- CQM – report criterion (aligned with CMS)

New Criteria

- Electronic Health Information (EHI) export
- Standardized API for patient and population services

- Privacy and Security Attestation Criteria

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Revised: United States Core Data for Interoperability Standard

The United States Core Data for Interoperability (USCDI) standard will replace the Common Clinical Data Set (CCDS) definition 24 months after publication of this final rule.

CCDS
↓
USCDI
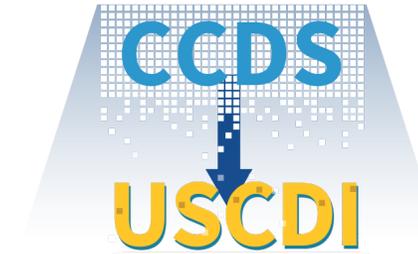
USCDI includes the following new required data classes and data elements:

Provenance

Clinical Notes

Pediatric Vital Signs

Address, Email & Phone Number

Health IT developers need to update their certified health IT to support the USCDI for all certification criteria affected by this change within 24 months after the publication of the final rule.

USCDI Standard Annual Update Schedule

ONC will establish and follow a predictable, transparent, and collaborative process to expand the USCDI, including providing stakeholders with the opportunity to comment on the USCDI's expansion.

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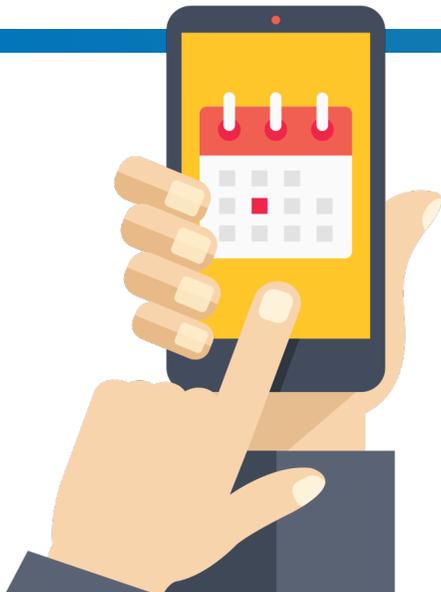
New: Electronic Health Information (EHI) Export Criterion

Adopted a focused definition of EHI to **ePHI** to the extent that it would be included in a **designated record set.**

For certification, Developers are required to ensure health IT products are capable of exporting the EHI that can be stored by the product at the time of certification.

General Requirements

A certified Health IT Module must include export capabilities for:

a) a single patient EHI export to support patient access and

b) patient population EHI export to support transitions between health IT systems

The export file(s) created must:

a) be electronic and in a computable format, and

b) the publicly accessible hyperlink of the export's format must be included with the exported file(s).

Note: Health IT developers have the flexibility to determine their products' standard format for the purpose of representing the exported EHI

New: Application Programming Interface (API) Criterion

- Established a new application programming interface (API) certification criterion that requires health IT developers to support standardized APIs for single patient and population services.

- Certification criterion is limited to API-enabled "read" services using the HL7® Fast Healthcare Interoperability Resources (FHIR) Release 4 standard.

- The use of the FHIR standard and a set of implementation specifications provides known technical requirements against which third-party apps can be developed.

Supports two types of API-enabled services:

» Services for which a **single patient's data** is the focus

» Services for which **multiple patients' data** are the focus

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Conditions and Maintenance of Certification Requirements

Conditions and Maintenance of Certification Requirements

The 21st Century Cures Act requires HHS to establish Conditions and Maintenance of Certification requirements for the ONC Health IT Certification Program.

Seven (7) Conditions of Certification with Maintenance of Certification Requirements

- Information Blocking

- Assurances

- Communications

- Application Programming Interfaces (APIs)

- Real World Testing

- Attestations

- *EHR Reporting Criteria Submission (at future time)*
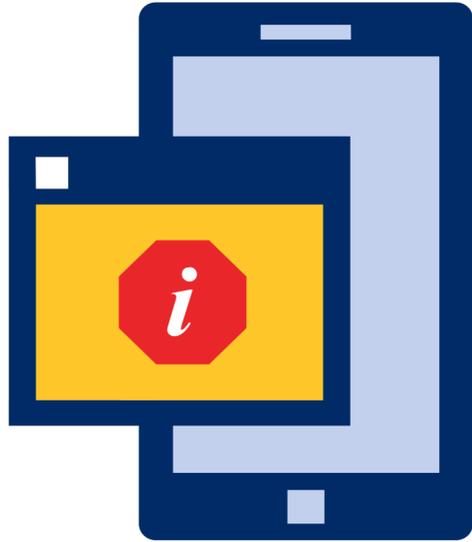
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Information Blocking

What Makes an Individual or Entity an Information Blocker?

Elements of information blocking

- ☐ Actor regulated by the information blocking provision

- ☐ Involves electronic health information (EHI)

- ☐ Practice is likely to interfere with, prevent, or materially discourage access, exchange, or use of EHI

- ☐ Requisite knowledge by the actor

- ☐ Not required by law

- ☐ Not covered by an exception

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"Actors" Regulated in the Final Rule

Health Care Providers

Health IT Developers of Certified Health IT
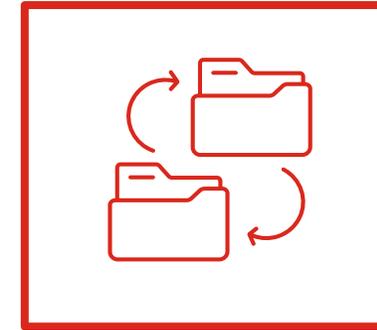
Health Information Networks (HIN)/ Health Information Exchanges (HIE)

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Health Care Providers
Who are they?

- hospital
- skilled nursing facility
- nursing facility
- home health entity or other long term care facility
- health care clinic
- community mental health center
- renal dialysis facility
- blood center
- ambulatory surgical

- emergency medical services provider
- federally qualified health center
- group practice
- pharmacist
- pharmacy
- laboratory
- physician
- practitioner
- rural health clinic
- ambulatory surgical center

- provider operated by, or under contract with, the Indian Health Service or by an Indian tribe, tribal organization, or urban Indian organization
- "covered entity" under certain statutory provisions
- therapist
- any other category of health care facility, entity, practitioner, or clinician determined appropriate by the Secretary

Health IT Developers of Certified Health IT
Who are they?

An individual or entity, other than a health care provider that self-develops health IT for its own use, that develops or offers health information technology and which has, **at the time it engages in a practice that is the subject of an information blocking claim, one or more Health IT Modules certified** under a program for the voluntary certification of health information technology that is kept or recognized by the National Coordinator.
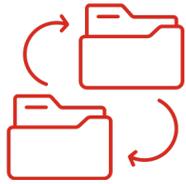
Health Information Networks & Exchanges
Who are they?

An individual or entity that determines, controls, or has the discretion to administer any requirement, policy, or agreement that permits, enables, or requires the use of any technology or services for access, exchange, or use of EHI:

1. Among **more than two unaffiliated individuals or entities** (other than the individual or entity to which this definition might apply) **that are enable to exchange with each other**; and

2. That is for a **treatment, payment, or health care operations** purpose, as such terms are defined in 45 CFR 164.501 regardless of whether such individuals or entities are subject to the requirements of 45 CFR parts 160 and 164.
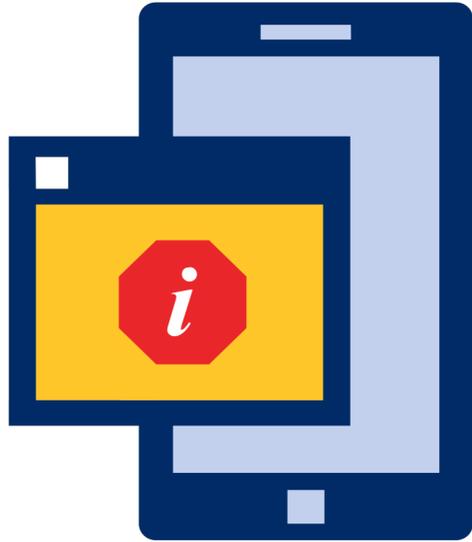
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Definition of Electronic Health Information (EHI)

- EHI means **electronic protected health information (ePHI)** to the extent that the ePHI is included in a **designated record set** as these terms are defined for HIPAA.

- This is applicable whether the actor is a covered entity or not.
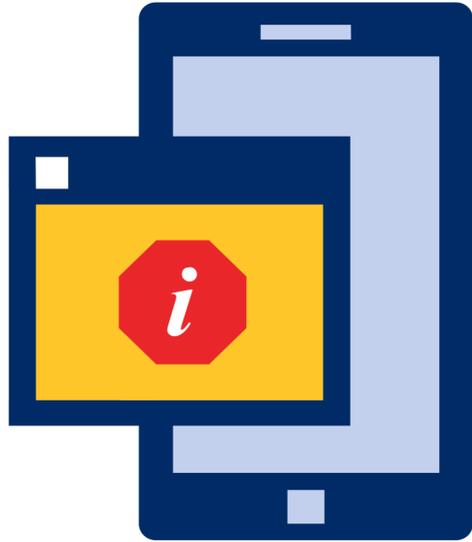
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"Interfere with" or "Interference" - What is it?

Interfere with or interference means to prevent, materially discourage, or otherwise inhibit.

- ***Publication of "FHIR service base URLs" (sometimes also referred to as "FHIR endpoints") -*** A FHIR service base URL cannot be withheld by an actor as it (just like many other technical interfaces) is necessary to enable the access, exchange, and use of EHI.

- ***Delays -*** An actor's practice of slowing or delaying access, exchange, or use of EHI could constitute an interference and implicate the information blocking provision.

- ***Costs for Electronic Access by Patients/Individuals -*** An actor's practice of charging an individual, their personal representative, or another person or entity designated by the individual for electronic access to the individual's EHI would be inherently suspect under an information blocking review.

"Interfere with" or "Interference" - What is it not?

Interfere with or interference means to prevent, materially discourage, or otherwise inhibit.

- **Business Associate Agreements (BAAs)** – Actors are **not** required to violate BAAs or associated service level agreements. *However*, a BAA or its associated service level agreements must not be used in a discriminatory manner by an actor to forbid or limit disclosures that otherwise would be permitted by the Privacy Rule.

- **Educate Patients about Privacy and Security Risks of Apps and 3ʳᵈ Parties –** Actors may provide patients with information that:

  - Focuses on any current privacy and/or security risks posed by the technology or the third-party developer of the technology;

  - Is factually accurate, unbiased, objective, and not unfair or deceptive; and

  - Is provided in a non-discriminatory manner.

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Knowledge Standard

Health Care Providers

"…**knows** that such practice is **unreasonable** and is likely to interfere with, prevent, or materially discourage the access, exchange or use of electronic health information…."

Health IT Developers of Certified Health IT and HINs/HIEs

"…**knows, or should know**, that such practice is likely to interfere with, prevent, or materially discourage the access, exchange or use of electronic health information…."

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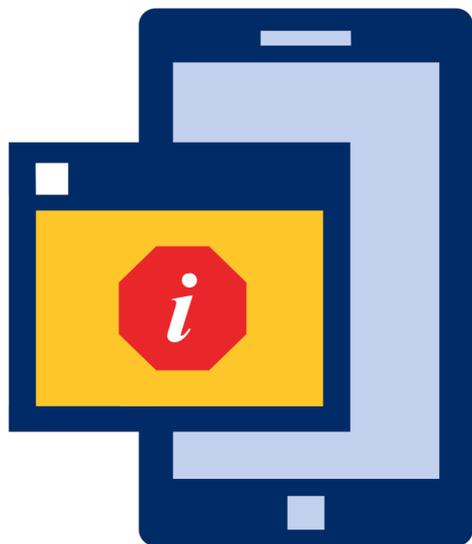
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Required by Law

What does it mean?

- Refers specifically to interferences with access, exchange, or use of EHI that are explicitly required by state or federal law.

- Distinguishes between interferences that are "required by law" and those engaged in pursuant to a privacy law, but which are <u>not</u> "required by law."

Federal and state law includes:

- Statutes, regulations, court orders, and binding administrative decisions or settlements, such as (at the Federal level) those from the FTC or the Equal Employment Opportunity Commission (EEOC)

- Tribal laws, as applicable

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Information Blocking Exceptions

Exceptions that involve not fulfilling requests to access, exchange, or use EHI

1. Preventing Harm Exception

2. Privacy Exception

3. Security Exception

4. Infeasibility Exception

5. Health IT Performance Exception

Exceptions that involve procedures for fulfilling requests to access, exchange, or use EHI

6. Content and Manner Exception

7. Fees Exception

8. Licensing Exception

Content and Manner Exception

Overview

It will not be information blocking for an actor to limit the content of its response to a request to access, exchange, or use EHI or the manner in which it fulfills a request, provided certain conditions are met.

**To satisfy this exception,
an actor must meet both of these conditions:**

Content condition

+

Manner condition

Objective

This exception provides clarity and flexibility to actors concerning the required content of an actor's response to a request to access, exchange, or use EHI and the manner in which the actor may fulfill the request. It supports innovation and competition by allowing actors to first attempt to reach and maintain market negotiated terms for the access, exchange, and use of EHI.
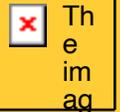
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Content and Manner Exception

Content Condition

1. **Up to 24 months** after the publication date of the final rule, an actor must respond to a request to access, exchange, or use EHI with, *at a minimum*, the EHI identified by the **data elements represented in the USCDI standard**.

2. **On and after 24 months** after the publication date of the final rule, an actor must respond to a request to access, exchange, or use EHI with **EHI as defined in § 171.102**.

Content and Manner Exception

Manner Condition – Any Manner Requested

- An actor must fulfill a request **in any manner** requested *unless* the actor is:

  1. Technically unable to fulfill the request in a manner requested; *or*

  2. Cannot reach agreeable terms with the requestor to fulfill the request.

- If an actor fulfills a request in **any manner requested**, the actor is **not** required to comply with the Fees or Licensing Exception.

Content and Manner Exception

Manner Condition – Alternative Manner

- If an actor responds in an **alternative manner**, the actor must fulfill the request **without unnecessary delay** in the **following order of priority**, only proceeding to the next consecutive paragraph if **technically unable** to fulfill the request in that manner:

    1. Using technology certified to standard(s) adopted in Part 170 that is specified by the requestor.

    2. Using content and transport standards specified by the requestor and published by:

        - Federal Government; or

        - Standards developing organization accredited by the American National Standards Institute.

    3. Using an alternative machine-readable format, including the means to interpret the EHI, agreed upon with the requestor.
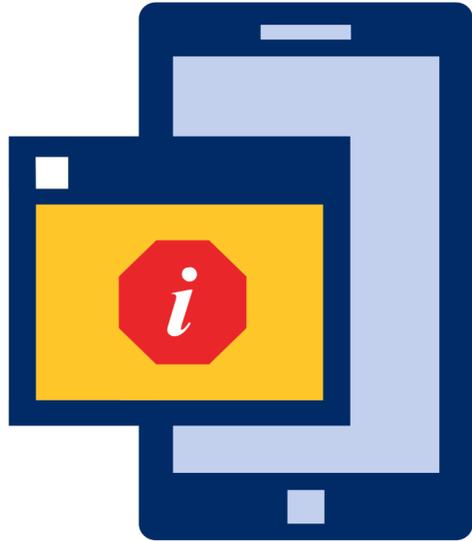
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Consequences of Being an Information Blocker

- **Cures Act prescribes penalties for information blocking**
  - Health IT developers of certified health IT, health information networks, and health information exchanges → Civil monetary penalties (CMPs) up to $1 million per violation
  - Health care providers → Appropriate disincentives

- **Certification ban (§ 170.581) for health IT developers in violation of the Conditions of Certification**
  - Information blocking Condition of Certification (§ 170.401)
  - Public listing of certification bans and terminations

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Please visit
www.healthit.gov/curesrule

- View the Final Rule

- Fact Sheets

- Upcoming Webinar Schedule

- Previously recorded webinars

- Additional resources
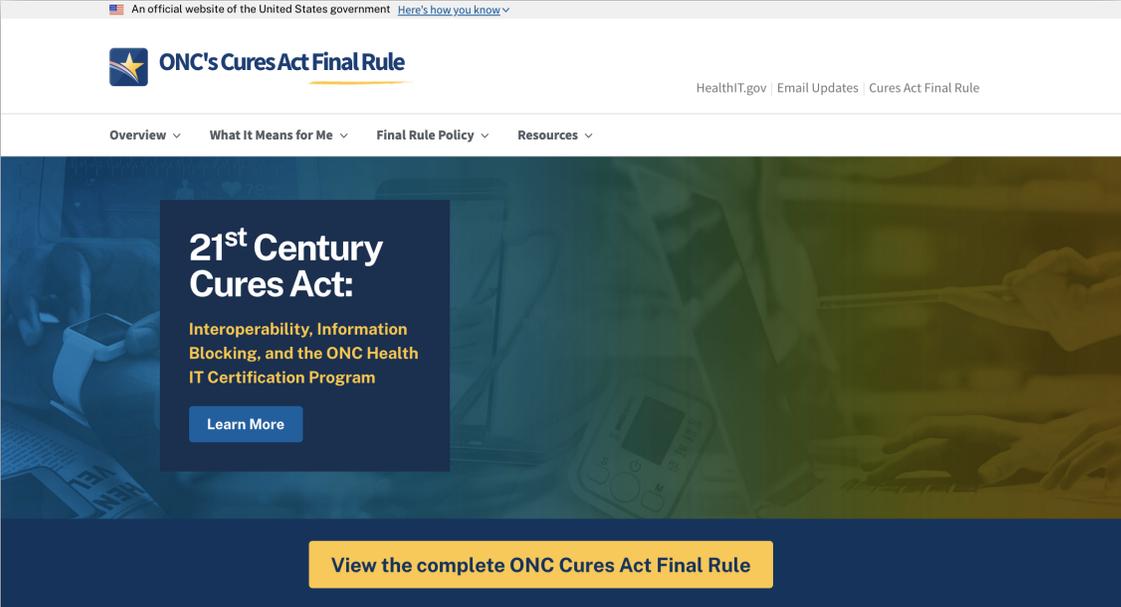
An official website of the United States government Here's how you know ⌄

ONC's Cures Act Final Rule

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Overview ⌄   What It Means for Me ⌄   Final Rule Policy ⌄   Resources ⌄

21st Century Cures Act:

Interoperability, Information Blocking, and the ONC Health IT Certification Program

Learn More

View the complete ONC Cures Act Final Rule

ONC's Cures Act Final Rule supports seamless and secure access, exchange, and use of electronic health information.

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♥ ONC Cures Act Final Rule	🖥 Interoperability
📈 Health IT Safety	👆 Usability
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